

§ 522.650 Dihydrostreptomycin sulfate injection.

(a) *Specifications.* Each milliliter contains dihydrostreptomycin sulfate equivalent to 500 milligrams of dihydrostreptomycin.

(b) *Sponsor.* See Nos. 000069 and 055529 in § 510.600(c) of this chapter.

(c) *National Academy of Sciences/National Research Council (NAS/NRC) status.* The conditions of use were NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter but may require bioequivalency and safety information.

(d) *Conditions of use—(1) Amount.* 5 milligrams per pound of body weight every 12 hours.

(2) *Indications for use.* Treatment of leptospirosis in dogs and horses due to *Leptospira canicola*, *L. icterohemorrhagiae*, and *L. pomona*; in cattle due to *L. pomona*; and in swine due to *L. pomona*; and *L. grippotyphosa*.

(3) *Limitations.* Administer by deep intramuscular injection only. Treatment should be continued for 3 to 5 days or until the urine is free of leptospira for at least 72 hours as measured by darkfield microscopic examination. Treatment with subtherapeutic dosages, excessive duration of therapy, or inappropriate use of this antibiotic may lead to the emergence of streptomycin or dihydrostreptomycin resistant organisms. Discontinue use 30 days before slaughter for food. Not for use in animals producing milk because use of the drug will contaminate the milk. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37331, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992]

§ 522.690 Dinoprost tromethamine sterile solution.

(a) *Specifications.* Each milliliter of sterile solution contains the equivalent of 5 milligrams of dinoprost.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Special considerations.* Women of child-bearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. Dinoprost tromethamine is readily

absorbed through the skin and can cause abortion and bronchospasms. Accidental spillage on the skin should be washed off immediately with soap and water. Use of this product in excess of the approved dose may result in drug residues. Do not administer to pregnant cattle unless abortion is desired. Do not administer intravenously; this may potentiate adverse reactions.

(d) *Conditions of use—(1) Mares—(i) Amount.* Equivalent of 1 milligram of dinoprost per 100 pounds of body weight.

(ii) *Indications.* For its luteolytic effect to control timing of estrus in estrus cycling mares and in clinically anestrus mares that have a corpus luteum.

(iii) *Limitations.* For use once as a single intramuscular injection. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cattle—(i) Amount.* 5 milliliters (equivalent to 25 milligrams of dinoprost).

(ii)(a) *Indications.* For its luteolytic effect to control timing of estrus and ovulation in estrous cycling cattle that have a corpus luteum.

(b) *Limitations.* For use in beef cattle and nonlactating dairy heifers, as follows: Inject a dose of 5 milliliters intramuscularly either once or twice at a 10- to 12-day interval. With a single injection, cattle should be bred at the usual time relative to estrus. With the two injections, cattle can be bred after the second injection either at the usual time relative to detected estrus or at about 80 hours after the second injection. Estrus is expected to occur 1 to 5 days after injection if a corpus luteum was present. Cattle that do not become pregnant to breeding at estrus on days 1 to 5 after injection will be expected to return to estrus in about 18 to 24 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(iii)(a) *Indications.* For treatment of pyometra (chronic endometritis).

(b) *Limitations.* For intramuscular use as a single injection. Federal law restricts this drug to use by or on the order of a licensed veterinarian.